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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,210	02/10/2005	Martin Beer	I-2002.014 US	3837

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INTERVET INC.  
PATENT DEPARTMENT  
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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/524,210

Applicant(s)

BEER ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12 is/are rejected.
- 7) ☒ Claim(s) 9-11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/10/05</u> | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This office action is in response to a preliminary amendment filed 2/10/05. Claims 1-11 have been amended. Claims 1-12 are pending in the application.

#### ***Information Disclosure Statement***

An IDS filed 2/10/05 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

#### ***Priority***

In a preliminary amendment filed 2/10/05, applicants have amended the priority data to read that the instant application is related to PCT/EP2003/009031, which claims priority to EP02078357.7, filed 8/13/02. The priority statement is objected to, as the phrase "is related to" does not properly indicate the relationship between the two applications. It would be remedial to recite that the instant application is -- a 371 of-- PCT/EP2003/009031

#### ***Specification***

The abstract of the disclosure is objected to because the abstract is >150 words. Correction is required. See MPEP § 608.01(b). As well, the abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

### ***Claim Objections***

Claim 1 is objected to for reciting “the part of the C and/or E1 protein” which is further referred to as a signal sequence. For clarity and consistency, it would be remedial to recite “a signal sequence of the C and/or E1 protein”.

Claim 9 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, claims 9-11 have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of “further downstream processing” are unclear. It is unclear what the term “further” is modifying. There are no recited steps for downstream processing that can comprise “further downstream processing and as such that is no antecedent basis for the phrase “**further** downstream processing”.

Claims 5 and 8 are vague and indefinite in that the metes and bounds of the amino acids positions that are deleted from C and E1 protein. Applicants recite specific amino acids that are deleted from the C and E1 protein. The metes and bounds of the deletions are unclear as the recited amino acids are said to be amino acids positions of C or E1 but according to the

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specification, the recited amino acids are in relation to the entire polypeptide. Secondly, BVDV is comprised of at least two isolates and multiple genetic groups for which the amino acid numbering is not completely conserved. As such amino acid numbering for BVDV1 would not be the same for every isolate or for BVDV2.

Claim 8 recites the limitation "The infectious viral particle" in claim 8. There is insufficient antecedent basis for this limitation in the claim. "The" should be replaced with the word -- An--.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Moorman et al (6,180,109; see entire document).

Moorman et al teach CFSV self-replicating RNA molecules (replicon) that express all structural proteins except a functional E1 protein. The replicon comprises a deletion of sequences within E1 such that the coding sequence retains the C-terminal sequences that encode the sequences responsible for downstream processing as recited in claims 1, 2 and 6 (see e.g. figure 5). The E1 protein is no longer functional as it does not express all epitopes of the protein.

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As well, infectious and vaccines are taught by Moorman et al (see e.g. figure 4, col 1, line 14-25) as recited in claims 8 and 12.

Claims 1-5, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Heinz et al (2004/0052818; see entire document).

Heinz et al teach pestivirus self-replicating RNA molecules (replicon), infectious clones and vaccines that express all structural proteins except a functional Capsid protein (see e.g. ¶ 0037, 0015 and claim 6). The replicon comprises a deletion of sequences within C such that the coding sequence retains the C-terminal sequences that encode the sequences responsible for downstream processing as recited in claims 1-4 and 8 (see e.g. ¶ 0015). Large deletions are disclosed such that functional C protein is not produced (see e.g. ¶ 0033). These mutants comprise from 5 to 70 amino acids and contemplate mutations from the N-terminus to prior to the signal for processing at the C-terminus. In the case of BVDV, this encompasses amino acids 201-243 as recited in claim 5 (see ¶ 0036).

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD  
Examiner  
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June 8, 2006



**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**